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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,506	10/03/2005	Mao-Hsiung Yen	U 015722-1	8980

140 7590 07/30/2010
LADAS & PARRY LLP
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EXAMINER	
PESELEV, ELLI	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
07/30/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nyuspatactions@ladas.com

Office Action Summary	Application No.	Applicant(s)	
	10/531,506	YEN ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,11,12,14,18,31,39,44-46,52-54 and 60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *11* is/are allowed.

6)☒ Claim(s) *1, 12, 14, 18, 31, 39, 44-46, 52-54 and 60* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 26, 2010 has been entered.

Claims 14, 18, 31, 39, 44-46, 52-54 and 60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for improvement in the condition of the patient and delay in the progression of the condition, does not reasonably provide enablement for prevention of the onset of the disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims.

The claims are directed to the methods of "treating". The term "treating" is defined in the specification (page 12, last two lines and page 13, lines 1-9) includes prevention of the onset of the disease. Such diseases include organ damage,

neurodegenerative diseases, cancer, and cardiac disorders as set forth on page 7 of the specification.

(B) The level of predictability in the art.

The are many factors which contribute to a development of the diseases encompassed by the present claims such as environmental factors and heredity factors. Therefore, here is a good reason to doubt a pharmaceutical agent useful in controlling overproduction of TNF-α or overproduction of superoxide anion radical will be effective in total prevention of a specific disease.

(C) The amount of direction provided by the inventor.

The inventor has failed to provide any evidence that the claimed methods are effective in preventing any diseases, the selection of subjects in needed of such prevention, and whether the prevention is achieved for a period of weeks, months, years or whether permanent prevention is achieved.

D) The existence of working examples.

No disclosure of any working examples directed to the prevention of any diseases.

(E) The quantity of experimentation needed to use the invention based on the content of the disclosure.

Because there is no way to predict a priori whether the claimed methods would be effective in preventing any diseases encompassed by said claims, it would take an undue amount of experimentation to determine whether the claimed methods are effective in preventing said diseases and for what period of time.

Claims 1, 12, 14, 18, 31, 44, 45 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in that two independent definations are set for variable R1 i.e. "R is H, lower alkyl, SO3H or PO3H2" and "OR1 is O(CH2)nY."

Claim 31 is indefinite in that variable X has not been defined. Also, there is no antecedent basis in the structural formula (v) for the variable X1.

There is no antecedent basis in claim 1 for the terminology "subject to the proviso that X3T is not OR', or NR'R' wherein R' and R' are each independently H, or lower alkyl".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31 and 45 are rejected under 35 U.S.C. 102(b) as being as anticipated by Lee et al (WO 01/30342 A1).

Lee et al disclose the claimed method of treating diseases associated with overproduction of THF-α or overproduction of superoxide anion radical (pages 14-16 and FOG. 1B). Note that FIG. !B depicts oroxylin A which reads on the compound encompassed by the present claim wherein R7 is H, R8 is methyl, R9 is H and X1 is H.

Claims 1, 12, 14, 18, 31, 39, 44, 53 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (WO 01/30342 A1).

Lee et al disclose a method of treating conditions resulting from the production of TNF-α or superoxide anion radicals with the compounds encompassed by the present claims (pages 14-16). It would have been prima facie obvious to a person having ordinary skill in the art at the time of the claimed invention to combine more than one such compound into a single composition because such a person would have expected the resulting composition to be useful for treating the same conditions.

Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's arguments filed April 26, 2010 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev
/Elli Peselev/
Primary Examiner, Art Unit 1623